II. Rejection Under 35 U.S.C. §102

The Examiner has rejected claim 13 under 35 U.S.C. §102(e). Specifically, the Examiner asserts that Applicants claim of (S)-4-{[3-2-(dimethylamino)ethyl-1H-indole-5-yl]methyl}-2-oxazolidine is anticipated by Robertson et al. in U.S. Patent No. 5,399,574. Applicants respectfully traverse this rejection.

To anticipate a claim, a single source must contain all the elements of the claim. See Hybritech Inc. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); Atlas Powder Co. v. E.I. du Pont De Newmours & Co., 750 F.2d 1569, 1574, 224 U.S.P.Q 409, 411 (Fed. Cir. 1984); In re Marshall, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (C.C.P.A. 1978). Moreover, the single source must disclose all of the claimed elements "arranged as claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989); Connell v. Sears Roebuck & Co., 722 F.2d 1542, 1548, 220 U.S.P.Q. 193, 198 (Fed. Cir. 1983). Robertson et al. do not disclose all the elements of the presently claimed invention. Claim 13 is directed to a **pure, non-solvated** (S)-N,N-dimethyl-2-[5-(2-oxo-1,3-oxazolidine-4-yl-methyl)-1H-indole-3-yl]ethylamine.

Applicants' invention is a novel one-pot synthesis process for preparing (S)-N,N-dimethyl-2-[5-(2-oxo-1,3-oxazolidine-4-yl-methyl)-1H-indole-3-yl]ethylamine. Applicants claimed invention allows the final product to be made at a high yield on a large scale (page 2, line 6-9 of the present application). Furthermore, the resulting product is a **non-solvated** solid of **high purity** (page 9, line 32). As an example on page 4 lines 7-9, the claimed invention provides a 6 step one-pot synthesis for the non-solvated pure

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(S)-N,N-dimethyl-2-[5-(2-oxo-1,3-oxazolidine-4-yl-methyl)-1H-indole-3-yl]ethylamine that suggests the isolation of only one intermediate--of the compound of formula (VI).

In the present case, Robertson et al. disclose a synthetic method for the preparation of (S)-N,N-dimethyl-2-[5-(2-oxo-1,3-oxazolidine-4-yl-methyl)-1H-indole-3-yl]ethylamine that is not only costly but also time-consuming due to isolation and purification of intermediates. According to Robertson et al., to arrive at the final composition (S)-N,N-dimethyl-2-[5-(2-oxo-1,3-oxazolidine-4-yl-methyl)-1H-indole-3-yl]ethylamine, the following intermediates require extraction and isolation techniques via column chromatography, particularly silica column chromatography:

- reduced intermediate of (S)-5-(4-Nitrobenzyl)-1,3-imidazolidin-2,4-dione
- reacted intermediate (S)-4-(4-Hydrazinobenzyl)-1,3-oxazolidin-2-one hydrochloride (column 16, line 8-11)
- reacted intermediate (S)-N,N-dimethyl-2-[5(2-oxo-1,3-oxazo-lidinylmethyl)-1H-indole-3-yl]ethylamine 0.9 isopropanolate 0.5 hydrate (column 17, lines 31-37)
- reacted intermediate (±)-3-[3-(1-Methyl-4-piperidyl)-1H-indol-5-yl]alamine (column 18, lines 32-35)
- reacted intermediate (±)-3-[3-(1-Methyl-4-piperidyl)-1H-indol-5-yl]-2-amino-1-propanol (column 18, lines 43-46)
- reacted intermediate (±)-3-(1-Methyl-4-piperidyl)-5-(2-oxo-1,3-oxazolidin-4-ylmethyl)-1H-indole (column 18, lines 56-59)

Applicants further direct the Examiner to column 15 lines 39 and 65-66 of Robertson et al. which discloses the use of phosgene and tin (II) chloride as a

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requirement for the synthesis of (S)-N,N-dimethyl-2-[5-(2-oxo-1,3-oxazolidine-4-yl-methyl)-1H-indole-3-yl]ethylamine. Phosgene ($COCl_2$) is a highly toxic gas or liquid that is classified as a pulmonary irritant and inhalation can cause fatal respiratory damage. Phosgene reacts violently and decomposes to toxic compounds on contact with moisture, including chlorine, carbon monoxide and carbon tetrachloride. Tin (II) chloride or stannous chloride, on the other hand is an environmentally hazardous reagent.

Applicants' claimed invention avoids the use of such dangerous reagents while carrying out the novel one-pot synthesis, thus resulting in a **pure, non-solvated** (S)-N,N-dimethyl-2-[5-(2-oxo-1,3-oxazolidine-4-yl-methyl)-1H-indole-3-yl]ethylamine. Because the Robertson et al. reference fails to teach a pure, non-solvated product, Robertson fails to anticipate the invention as claimed. Withdrawal of this rejection is respectfully requested.

III. Abstract of the Present Application

Applicants attach on a separate sheet, an abstract of the disclosure as required by the Examiner. The abstract conforms to the 37 C.F.R. §1.72(b) and no new matter has been added. Support for the abstract can be found on pages 2-4 of the present application.

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

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Respectfully submitted,

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Dated: September 13, 2001

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